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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,612	03/13/2001	Mie Takahashi	43890-475	7340

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EXAMINER
COUNTS, GARY W

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 06/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/743,612	Applicant(s) TAKAHASHI ET AL.	
	Examiner Gary W. Counts	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 March 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16,18,20-24,26 and 27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16, 18, 20-24, 26 and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Status of the claims

The amendment filed March 31, 2003 is acknowledged and has been entered.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-16, 18, 20 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, line 10 "said reaction area" is vague and indefinite because applicant recites two or more reaction areas out of said plurality of reaction areas. Which single reaction area is applicant referring to?

Claim 1, line 10 "cover" is vague and indefinite. It is unclear what applicant intends. Does the reaction areas cover the entire reaction layer or does it cover portions of the reaction layer.

Claim 1 is vague and indefinite because it is unclear how the coloration is achieved. Applicant recites a labeling reagent holding layer. However, applicant recites in lines 13 and 14 that the coloration occurs in the specific reaction between said binding reagent and said analytes. The binding reagent applicant is referring to is in the reaction area not the labeling reagent holding layer. It is unclear what the function of the labeling reagent is and also how coloration occurs without the use of the labeling reagent.

Claim 3 the phrase "sheet-like" is vague and indefinite. The phrase "-like" renders the claim indefinite because the claim includes elements not actually disclosed "those encompassed by "-like"), thereby rendering the scope of the claim unascertainable. See MPEP 2173.05(d). See also deficiency found in claim 4.

Claim 5 the phrases "dot-like" and "spots-like" is vague and indefinite. The phrase "- like" renders the claim indefinite because the claim includes elements not actually disclosed "those encompassed by "-like"), thereby rendering the scope of the claim unascertainable. See MPEP 2173.05(d).

Claim 15 is vague and indefinite because Applicant recites a labeling reagent holding layer. It is unclear if the labeling reagent is part of the detection process because there is no positive step in which the labeling reagent binds to the analyte or a corresponding binding reagent. See also deficiency in claim 16.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 2, 6-9, 15, 16, 18, 22, 23 27 are rejected under 35 U.S.C. 102(e) as being anticipated by Kuo et al (US 6,183,972).

Kuo et al disclose a method and device for determining the concentration of an analyte in a test fluid by immunochrmatography. Kuo et al disclose applying a sample to a test matrix (on a sample loading area), which can be in the form of a strip. Kuo et al disclose that the strip can be formed of non-bibulous or bibulous materials. Kuo et al disclose that the strip comprises a region having mobile specific binding partner for the analyte, which bears a detectable label (reagent labeling holding layer) and can react with analyte present in the fluid to form an analyte/labeled binding partner complex. Kuo et al disclose detection regions (reaction areas) which contain immobilized antibodies specific for an epitope of the analyte. These detection regions form a capture region (reaction layer)(Figure 1, #4). Kuo et al also disclose an absorbent pad (absorbtion layer) on the test strip. Kuo et al disclose detecting the labeled antibody to quantitatively determine the concentration of analyte. Kuo et al disclose the antibody label is capable of reflecting light at a predetermined wavelength and providing a reflectance spectrometer having a detector of reflectance intensity with means for moving the developed strip and detector relative to each other such as a specimen table on which the strip is placed which can be moved laterally under the read head of the detector. Kuo et al disclose that this provides in providing accurate quantitation. Kuo et al disclose that the detector can be under microprocessor control and that desired regions can be determined and then combined with preprogrammed software to provide a monotonous dose-response curve for the quantitative determination of an analyte (col 3-5).

With respect to the reaction areas formed so as to cover the reaction layer. Kuo et al teaches reaction areas on the reaction layer. Therefore, Kuo et al anticipates covering the reaction layer with reaction areas.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 3, 4, 10, 12-14, 20 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuo et al (US 6,183,972) in view of Chandler et al (US 6,271,046).

See above for teachings of Kuo et al.

Kuo et al differ from the instant invention in failing to specifically teach that the chromatographic strip includes a sheet-like solid support.

Chandler et al disclose an immunochromatographic test strip which comprises a backing sheet (sheet-like solid support). Chandler et al discloses that this backing sheet facilitates the advantage of handling of the immunchromatographic strip (col 7, lines 35-62).

It would have been obvious to one of ordinary skill in the art to incorporate a backing sheet as taught by Chandler et al into the chromatographic strip of Kuo et al because Chandler et al shows that such a backing sheet facilitates the advantage of handling the chromatographic strip.

7. Claims 5, 11 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuo et al (US 6,183,972) in view of Chandler et al (US 6,271,046) as applied to claims above, and further in view of Catt et al (US 6,235,241).

See above for teachings of Kuo et al and Chandler et al.

Kuo et al and Chandler et al differ from the instant invention in failing to teach the reaction areas are a plurality of spots.

Catt et al disclose the detectable material in a precisely-defined region (detection zone) can be placed in the form of a narrow line or dot (col 6). Catt et al disclose that the immobilization of specific binding reagent in this manner provides for a simple and cost effective manner for determining an analyte of interest.

It would have been obvious to one of ordinary skill in the art to incorporate the use of dot immobilized specific binding reagent as taught by Catt et al into the modified method and device of Kuo et al because Catt et al show that the immobilization of specific binding reagent in this manner provides for a simple and cost effective manner for determining an analyte of interest.

Response to Arguments

Applicant's arguments filed March 31, 2003 have been fully considered by they are not persuasive.

Applicant argues that the phrase "- like" is not indefinite. Applicant specifically points of that the ordinary meaning of the term "like" as used in the objected to phrases means "the same or nearly the same (as in appearance, character, or quantity)." The 112 rejection stands for reason of record and further because the definition for the

phrase is not provided in the specification and as noted above the claim includes elements not actually disclosed.

Applicant argues that the Kuo et al reference does not teach that the reaction layer includes a plurality of reaction areas within the reaction layer and that each reaction are retain a bind reagent. This is not found persuasive because as disclosed above Kuo et al disclose detection regions (reaction areas) which contain immobilized antibodies specific for an epitope of the analyte. These detection regions form a capture region (reaction layer)(Figure 1, #4). Therefore, Kuo teaches a reaction layer comprising a plurality of reaction areas.

Applicant further argues that Kuo et al does not teach reaction areas having a plurality of spots. Examiner agrees that Kuo et al does not teach this limitation. However, since the recited claim recites wherein said reaction area is formed so as to cover said reactive layer **or** disposed uniformly over said reactive layer in a spot or dot shape. Kuo et al anticipates the limitation of the reaction area is formed so as to cover the reactive layer.

Applicant argues that the rejections based on Chandler et al are improper because all of the rejected claims are dependent claims and that none of the base claims upon which these claims depend have been rejected. Applicant further argues that the Chandler reference does not make up for the deficiencies of Kuo et al. This is not found persuasive because as disclosed above Kuo et al anticipates the instantly recited claims, including base claims 1, 15 and 22. Chandler et al specifically teaches the advantages of using a backing sheet (sheet-like solid support) (col 7, lines 35-62.

Therefore, it is the Examiner position that the Kuo et al reference in combination with the Chandler et al reference teach the instantly recited claims.

Applicant argues that the rejections based on Catt et al are improper because all of the rejected claims are dependent claims and that none of the base claims upon which these claims depend have been rejected. This is not found persuasive because as disclosed above Kuo et al anticipates the recited claims, including base claims 1, 15, and 22. Applicant argues that Catt et al disclose a defined region (detection zone) can be placed in the form of a narrow line or dot...." And that the claims require more that a single dot and that there is no suggestion or motivation from the teachings of Catt et al. to employ a plurality of spots or dots or to provide for a plurality of reaction areas within a reaction layer. This is not found persuasive because of reason set forth above and further because Kuo et al teaches multiple reaction areas in the form of a line. Kuo et al also teaches that these multiple reaction areas or within a capture region (reaction layer). Examiner takes Official Notice of the equivalence of a line or dot as a detection zone for use in immunochrmatographic assay art and that the selection of this known equivalent to replace the lines of the Kuo et al reference would be within the level of ordinary skill in the art. And one of ordinary skill in the art would recognize that the replacement of the multiple reaction areas (lines) of Kuo et al with the dot of Catt et al would provide for multiple reaction dots as recited in the claims. Therefore, it is the Examiner's position that the combination of Kuo et al, Chandler et al and Catt et al is proper.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (703) 305-1444. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-4242 for regular communications and (703)3084242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gary W. Counts
Examiner
Art Unit 1641
June 3, 2003

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641